

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

RICHARD HART and MARIE LOUISE
TRUDEL-HART,

Plaintiffs,

v.

U.S. BANK NATIONAL ASSOCIATION
and SEKISUI AMERICA CORPORATION,

Defendants.

ECF CASE

Civil Action No. 12-CV-3560 (SAS)

ANSWER AND COUNTERCLAIMS

Defendant Sekisui America Corporation (“SAC”), by its attorneys Morrison & Foerster LLP, answers the complaint of Plaintiffs Richard Hart (“Hart”) and Marie Louise Trudel-Hart (“Trudel-Hart,” and, collectively with Hart, “Plaintiffs” or “Plaintiffs-Counterclaim Defendants”), dated May 4, 2012, in the above-captioned action (the “Complaint”), and asserts its counterclaims against Plaintiffs as follows:

1. Denies the allegations in Paragraph 1 of the Complaint except admits that Plaintiffs have brought this action seeking relief and that U.S. Bank National Association is the holder of funds in escrow pursuant to an agreement including SAC and Hart.
2. Denies the allegations in Paragraph 2 of the Complaint.
3. Denies the allegations in Paragraph 3 of the Complaint except admits that SAC sent a Claim Notice for Indemnification from the Principal Shareholders on October 14, 2010 pursuant to the terms of the parties’ agreement.
4. Denies the allegations in Paragraph 4 of the Complaint except admits that Plaintiff Hart sent a letter to SAC on or about November 9, 2010.

5. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5 of the Complaint.

6. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 6 of the Complaint.

7. Admits the allegations in Paragraph 7 of the Complaint.

8. Avers that the allegations in Paragraph 8 of the Complaint are legal conclusions to which no response is required.

9. Avers that the allegations in Paragraph 9 of the Complaint are legal conclusions to which no response is required.

10. Avers that the allegations in Paragraph 10 of the Complaint are legal conclusions to which no response is required.

11. Avers that the allegations in Paragraph 11 of the Complaint are legal conclusions to which no response is required.

12. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 12 of the Complaint.

13. Denies the allegations in Paragraph 13 of the Complaint and refers to the Stock Purchase Agreement, attached as Exhibit B to the Complaint, for its terms.

14. Denies the allegations in Paragraph 14 of the Complaint and refers to the Stock Purchase Agreement, attached as Exhibit B to the Complaint, for its terms.

15. Denies the allegations in Paragraph 15 of the Complaint and refers to the Stock Purchase Agreement, attached as Exhibit B to the Complaint, for its terms.

16. Denies the allegations in Paragraph 16 of the Complaint and refers to the Stock Purchase Agreement, attached as Exhibit B to the Complaint, for its terms.

17. Denies the allegations in Paragraph 17 of the Complaint and refers to the Stock Purchase Agreement, attached as Exhibit B to the Complaint, for its terms.

18. Denies the allegations in Paragraph 18 of the Complaint and refers to the Escrow Agreement, attached as Exhibit A to the Complaint, for its terms.

19. Denies the allegations in Paragraph 19 of the Complaint and refers to the Escrow Agreement, attached as Exhibit A to the Complaint, for its terms.

20. Admits the allegations in Paragraph 20 of the Complaint.

21. Denies the allegations in Paragraph 21 of the Complaint and refers to the Escrow Agreement, attached as Exhibit A to the Complaint, and the Stock Purchase Agreement, attached as Exhibit B to the Complaint, for their terms.

22. Denies the allegations in Paragraph 22 of the Complaint, except admits that SAC sent Plaintiffs a Claim Notice for Indemnification from the Principal Shareholders on October 14, 2010, attached as Exhibit C to the Complaint.

23. Denies the allegations in Paragraph 23 of the Complaint and refers to the Claim Notice for Indemnification from the Principal Shareholders, attached as Exhibit C to the Complaint, for a complete recitation of its terms.

24. Denies the allegations in Paragraph 24 of the Complaint and refers to the Claim Notice for Indemnification from the Principal Shareholders, attached as Exhibit C to the Complaint, for its terms.

25. Denies the allegations in Paragraph 25 of the Complaint and refers to the Indemnification Claim Certificate of Instruction, partially attached as Exhibit D to the Complaint, for its terms.

26. Denies the allegations in Paragraph 26 of the Complaint and refers to the Notice that Principal Shareholders Dispute Claim Notice of Purchaser, attached as Exhibit E to the Complaint, for its terms.

27. Denies the allegations in Paragraph 27 of the Complaint and refers to the Notice that Principal Shareholders Dispute Claim Notice of Purchaser, attached as Exhibit E to the Complaint, for its terms.

28. Denies the allegations in Paragraph 28 of the Complaint and refers to the Indemnification Claim Objection Certificate, attached as Exhibit F to the Complaint, for its terms.

29. Denies the allegations in Paragraph 29 of the Complaint and refers to the Claim Notice for Indemnification from the Principal Shareholders, attached as Exhibit C to the Complaint, and the Indemnification Claim Certificate of Instruction, partially attached as Exhibit D to the Complaint, for their terms.

FIRST CAUSE OF ACTION

Breach of Contract

30. SAC hereby repeats and incorporates its responses to each of the aforementioned allegations as if fully set forth herein.

31. Denies the allegations in Paragraph 31 of the Complaint.

32. Denies the allegations in Paragraph 32 of the Complaint.

33. Denies the allegations in Paragraph 33 of the Complaint and refers to the Escrow Agreement, attached as Exhibit A to the Complaint, for its terms.

34. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 34 of the Complaint.

35. Denies the allegations in Paragraph 35 of the Complaint.

AFFIRMATIVE DEFENSES

As and for its affirmative defenses, SAC alleges as follows, without assuming any burden of pleading or proof that would otherwise rest with Plaintiffs, and without waiving and hereby expressly reserving the right to assert any and all additional defenses at such time and to such extent as discovery and factual developments establish a basis therefore:

FIRST AFFIRMATIVE DEFENSE

36. The Complaint fails, in whole or in part, to state a claim against SAC upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

37. The relief sought in the Complaint is barred because Plaintiffs have breached the terms of the Stock Purchase Agreement and/or the Escrow Agreement.

THIRD AFFIRMATIVE DEFENSE

38. The relief sought in the Complaint is barred because Plaintiffs have failed to satisfy the requirements of the Stock Purchase Agreement and/or the Escrow Agreement.

FOURTH AFFIRMATIVE DEFENSE

39. The relief sought in the Complaint is barred because of Plaintiffs' fraud.

FIFTH AFFIRMATIVE DEFENSE

40. The relief sought in the Complaint is barred, in whole or in part, by the doctrine of laches.

SIXTH AFFIRMATIVE DEFENSE

41. The relief sought in the Complaint is barred, in whole or in part, by the doctrines of waiver and/or equitable estoppel.

SEVENTH AFFIRMATIVE DEFENSE

42. The relief sought in the Complaint is barred, in whole or in part, by the doctrine of unclean hands.

EIGHTH AFFIRMATIVE DEFENSE

43. The relief sought in the Complaint is barred, in whole or in part, because Plaintiffs have not suffered any damages or harm.

NINTH AFFIRMATIVE DEFENSE

44. The relief sought in the Complaint is barred, in whole or in part, because Plaintiffs have failed to mitigate damages, if any.

COUNTERCLAIMS

SAC asserts the following counterclaims:

ADDITIONAL FACTS RELATED TO COUNTERCLAIMS

45. Upon information and belief, American Diagnostica, Inc. (“ADI”) was co-founded by Hart in 1982. He was the company’s President and principal owner, along with Trudel-Hart, and was in charge of the day-to-day operations of the company. Upon information and belief, in or around October 2007, Hart began his search for a buyer in order to cash out on the family business.

46. In or around September 2008, Crosstree Capital Partners (“Crosstree”), ADI’s advisory company, contacted Sekisui Medical Co., Ltd. (“SMD”), SAC’s sister

corporation, to inquire about its interest in acquiring ADI. Plaintiffs-Counterclaim Defendants owned approximately 96% of ADI at the time.

47. Shortly thereafter, on or around October 21, 2008, SMD signed a confidentiality agreement and received a “Confidential Memorandum,” dated August 2008.

48. The Confidential Memorandum contained extensive information about ADI and its financial situation. Of particular significance was its discussion of a product in ADI’s pipeline known as FEMTELLE. According to the Confidential Memorandum:

FEMTELLE is a proteomic breast cancer test that remains the only breast cancer test to have been accorded Level-of-One Evidence for its two breast cancer biomarkers At present, FEMTELLE is used only in Europe but ranks eighth among all of the Company’s product families in FY 2008 revenue. . . . While the FEMTELLE assay is experiencing overall growth in usage in its current markets, management believes that introduction of FEMTELLE into the U.S. market will drive substantial future revenue growth for this product, and the ADI Group has conducted a number of discussions with the U.S. FDA and submitted an application for 510(k) clearance which the Company expects to receive by the fourth quarter of FY 2009.

49. The Confidential Memorandum included projections for FEMTELLE’s average U.S. sales price at \$600, with gross margins projected at a whopping 85%. In addition, according to information provided by ADI and included in the Confidential Memorandum, FEMTELLE was expected by 2013 to account for over 80% of ADI’s Earnings Before Income Tax, Depreciation, and Amortization (EBITDA)—regarded as a key indicator of economic value.

50. On or around December 1, 2008, after reviewing the financial information provided by Crosstree, SMD sent Hart a Letter of Intent to purchase ADI that included a proposed \$24 million upfront payment for ADI’s core business and a separate

\$1.5 million upfront payment for FEMTELLE, as well as a potential earn out if FEMTELLE reached certain future milestones and revenue targets.

51. On or around December 10, 2008, SMD and Plaintiffs-Counterclaim Defendants executed a revised Letter of Intent, this time incorporating the separate FEMTELLE payment into the purchase price, with the upfront payment remaining at \$25.5 million, including FEMTELLE, as well as a revised earn out schedule for FEMTELLE base on future milestone and revenue targets.

52. Following the execution of the Letter of Intent, SMD and SAC retained KPMG to perform due diligence of ADI prior to finalizing the acquisition. Through this process, KPMG learned that less than a week before the Confidential Memorandum was provided to SMD, Hart had fired ADI's long-standing Chief Financial Officer of 12 years, along with two junior accountants, because of an alleged "disagreement" with Hart.

53. KPMG reported to SAC that while the new ADI accounting staff—without its long-standing CFO—appeared to be adequately handling the day-to-day operations of the company, they "did not have a detail[ed] understanding of complex or historical accounting matters," and that there was a "lack of knowledge of the current accounting staff." SAC was thus deprived of access to key financial personnel during the diligence process.

54. In addition, KPMG reported that ADI "had not provided [KPMG] with several key documents. There were also several open questions which [KPMG] presented to management that they were unable to answer."

55. While the lack of cooperation and knowledge of ADI's management by itself may have been indicative of intent to hide the truth, SAC had no further reason at that time to suspect Plaintiffs-Counterclaim Defendants were intentionally omitting material information from SAC. As it turned out, however, Plaintiffs-Counterclaim Defendants' deceitful acts ran deeper. In addition to Hart firing the CFO and members of the accounting staff just prior to engaging in discussions with SMD and SAC, SAC later learned that ADI's primary contact with the FDA was never made available to KPMG during the due diligence period.

56. As a result of this lack of access to material information, KPMG was unable to analyze sufficiently and debunk the financial data and information provided by ADI. SAC never learned until much later that the FEMTELLE financial projections in particular were grossly overstated by ADI's advisors, and that ADI had actually previously filed a FEMTELLE 510(k) submission with the FDA in 2007, which was effectively rejected.

57. On or about March 5, 2009, SAC entered into the Stock Purchase Agreement with Plaintiffs-Counterclaim Defendants and the other shareholders of ADI to purchase the shares of ADI.

58. Pursuant to the Stock Purchase Agreement, SAC agreed to pay, and did pay, \$25,500,000 in cash to the Plaintiffs-Counterclaim Defendants and other ADI shareholders for their shares of ADI, with \$3,825,000 of the purchase price transferred into an escrow account.

59. Under the terms of the Stock Purchase Agreement, Hart and Trudel-Hart were defined as the Principal Shareholders, and together received 95.94% of the purchase price.

60. As an inducement for SAC to enter into the Stock Purchase Agreement and pay the \$25.5 million purchase price, the Plaintiffs-Counterclaim Defendants, as Principal Shareholders, made several representations and warranties regarding ADI, its products, assets, operations, facilities and customers. In particular, Plaintiffs-Counterclaim Defendants warranted that:

- a. “Each Product has been in conformity in all material aspects with all applicable contractual commitments and warranties. There are no material design, manufacturing or other defects, latent or otherwise, with respect to any Products” (Paragraph 4.11);
- b. “The buildings, plants, leasehold improvements, structures, facilities, equipment and other property and assets which are owned, leased or used by the Company or any of its Subsidiaries are (a) sufficient to conduct . . . the Business as currently conducted and currently proposed to be conducted, (b) conform in all material respects to all Laws and Permits relating to their construction, use and operation and (c) . . . are in good operating condition, ordinary wear and tear excluded.” (Paragraph 4.12);
- c. “The Company and its Subsidiaries are, and have since January 1, 2006 been, in compliance in all material respects with all applicable Laws.” (Paragraph 4.14(a));
- d. “[T]he Company holds all Permits which are required under the applicable Laws for the Products currently marketed by the Company or any subsidiary thereof and the conduct of the Company’s testing, manufacturing, marketing, sales and distribution activities for the Products (collectively, ‘Product Registrations’). All Product Registrations are in full force and effect and none of the Product Registrations have been withdrawn, revoked, suspended, cancelled, subject to FDA integrity review or put on clinical hold, nor is any such withdrawal, revocation, suspension, cancellation, integrity review or clinical hold pending, or, to the Knowledge of the Company, threatened. . . . All (i) correspondence with Governmental Entities relating to the Products, (ii) Product Registrations and associated records and

correspondence (together with all supporting documentation), (iii) data and information related to non-clinical and clinical testing of Products, (iv) promotional literature and advertising materials (with support data) relating to the Products, (v) design history files, complaints, medical device reports, medical device reports event files, correction and removal reports, and (vi) memoranda or records (including engineering change orders) documenting decisions not to file a 510(k) pre-market notification with respect to any of the Products have been maintained in all material respects in accordance with sound business practices and complete and correct copies thereof have been made available to the Purchaser by the Company.” (Paragraph 4.14(c));

- e. “The Products are not misbranded or adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321 et seq.” (Paragraph 4.14(d));
- f. “Neither the Company, any Subsidiary thereof, either Principal Shareholder nor any of their respective Affiliates or Representatives have . . . made an untrue statement of material fact or fraudulent statement to the FDA or any other Governmental Entity or notified body with respect to any Product tested, manufactured, distributed or sold by the Company, any of its Subsidiaries or any of their respective Affiliates, or failed to disclose a material fact required to be disclosed to any Governmental Entity or notified body with respect to any Product tested, manufactured, distributed or sold by the Company or any Subsidiary thereof.” (Paragraph 4.14(f)); and
- g. “(a) [T]he relationships of each of the Company and its Subsidiaries with each Key Customer are good commercial working relationships; (b) no Key Customer has cancelled or otherwise terminated or, to the Knowledge of the Company, threatened to cancel or otherwise terminate, its relationship with the Company or any of its Subsidiaries, in each case, by written or, to the Knowledge of the Company, other notification; (c) neither the Company nor any of its Subsidiaries has received any written or, to the Knowledge of the Company, other notice from any Key Customer to the effect that any such Key Customer intends to terminate, renegotiate, materially reduce or otherwise materially and adversely modify its relationship with the Company or any of its Subsidiaries; and (d) neither the Company nor any of its Subsidiaries have been involved in any material dispute with a Key Customer.” (Paragraph 4.26.)

61. According to the Stock Purchase Agreement, “notwithstanding any right of any party, whether or not exercised, to investigate the affairs or the accuracy of the representations and warranties contained herein of any other party hereto, each party hereto has the right to rely fully on the representations, warranties, covenants and agreements of each other party contained herein.” (Paragraph 9.1.)

62. Plaintiffs-Counterclaim Defendants further agreed to pay SAC for all losses—including attorneys’ fees—suffered or incurred by SAC “resulting from, arising out of or relating to . . . any breach of any of the representations or warranties” (Paragraph 9.3(a).)

63. SAC’s primary motivation for acquiring ADI was the prospect of marketing FEMTELLE in the United States. Plaintiffs-Counterclaim Defendants were well aware of this motivation; indeed, Crosstree heavily promoted the future prospects of FEMTELLE and, in fact, on information and belief, grossly overstated FEMTELLE’s potential value in an attempt to lure SAC as a buyer and drive up the purchase price.

64. Prior to marketing FEMTELLE in the U.S., under Section 510(k) of the Food, Drug and Cosmetic Act, ADI was required to file a premarket notification with the FDA at least 90 days in advance of its intent to market FEMTELLE.

65. During the parties’ negotiations for ADI, SAC was informed that the process of preparing FEMTELLE’s 510(k) premarket notification was well underway, and it was expected that the submission would be filed with the FDA shortly and approved by the fourth quarter of 2009. The Stock Purchase Agreement also contained language presuming that the 510(k) would be filed the same year, defining “FEMTELLE Clearance” as “the FDA 510(k) clearance of the FEMTELLE Products, as described in

the original 510(k) premarket notification submitted by the Company to the FDA in 2009 under an FDA determined reference number (*to be assigned following submission*)”

(Paragraph 1.1.)

66. As planned, on or about March 15, 2009, shortly after execution of the Stock Purchase Agreement and prior to the closing of the parties’ transaction on April 20, 2009, ADI submitted a 510(k) premarket notification for FEMTELLE to the FDA. The FEMTELLE 510(k) was based entirely on studies and tests allegedly conducted by ADI prior to SAC’s acquisition of ADI.

67. Unbeknownst to SAC, however, and well known to Plaintiffs-Counterclaim Defendants, the FEMTELLE 510(k) application had little chance of success. In 2007, Plaintiffs-Counterclaim Defendants and ADI had previously submitted a FEMTELLE 510(k) based on the same studies and tests, which was deemed withdrawn by the FDA on or around May 19, 2008 because the information provided by Plaintiffs-Counterclaim Defendants and ADI was insufficient.

68. Not surprisingly, on or about May 27, 2009—after the parties’ transaction had closed—the FDA replied to the FEMTELLE 510(k) submission and requested substantial additional information regarding clinical studies, analytical studies, device history, and other subjects.

69. Before long, it became clear—as Plaintiffs-Counterclaim Defendants were undoubtedly well aware—that ADI lacked the current materials necessary to satisfy the FDA’s 510(k) requirements, and ADI had no option but to formally withdraw the FEMTELLE 510(k) submission on or about June 29, 2010.

70. Following the parties' transaction, Hart had initially remained the CEO of ADI, and Vince Forte, ADI's Manager of Manufacturing since 1992, had been promoted to Vice President.

71. On or around March 31, 2010, Mr. Forte left ADI, and Kevin Morrissey was hired as the new Director of Manufacturing.

72. Once Mr. Morrissey arrived, he discovered a number of discrepancies in ADI's product records and problems with the products themselves, including that ADI had been using expired raw materials in certain products. Mr. Morrissey immediately reported these issues to Hart.

73. Hart did nothing in response. Instead, on or about April 9, 2010, Hart left on sick leave for minor surgery, and refused to return to the office.

74. At this point, ADI's numerous operational deficiencies started to become apparent. SAC began to realize that ADI was nowhere near the company that Plaintiffs-Counterclaim Defendants had contractually represented it to be.

75. Mr. Morrissey retained the services of quality solutions consultants to review ADI's operations. The consultants identified further defects, which existed prior to SAC's acquisition.

76. Specifically, throughout 2010, SAC uncovered numerous breaches in Plaintiffs-Counterclaim Defendants' representations and warranties about the operations of ADI at the time of SAC's purchase. Such breaches include, but are not limited to:

- a. The FDA-regulated In-Vitro Diagnostic ("IVD") products manufactured at the ADI facility either were not validated or validation was not documented as required by FDA regulations. SAC had to spend money and

resources to validate all of these products and conduct the necessary stability testing in accordance with FDA regulations.

b. ADI's lyophilizers were not validated properly as required by FDA regulations. ADI did not establish appropriate validation protocols and failed to validate certain processes and equipment. SAC had to purchase new equipment to meet FDA minimum standards.

c. ADI's environmental controls were not in compliance with FDA requirements, particularly those related to ADI's "Clean Room" (an environment, typically used in manufacturing or scientific research, that has a low level of environmental pollutants such as dust, airborne microbes, aerosol particles and chemical vapors), on which SAC had to spend time and money to remedy.

d. Several ADI products were found to contain raw material that was unfit for sale. As a result, SAC had to scrap non-conforming products, purchase replacement raw materials and dispose of the scrapped non-conforming goods.

e. ADI had failed to maintain design files for almost all of its products in violation of the FDA's Good Manufacturing Process (GMP) regulations. In particular, none of ADI's devices had device master records ("DMRs") that met FDA requirements. The design history records ("DHRs") (i.e., batch records) also did not meet FDA requirements prior to the SAC acquisition. GMP regulations require DMRs for each device, which include the following information: device specifications; process specifications; quality assurance procedures and specifications; packaging and labeling specifications; and installation, maintenance, and servicing procedures and methods. ADI was

also required to maintain DHRs for manufactured batches or lots to demonstrate that the devices are manufactured in accordance with the DMRs and GMP requirements. SAC is in the process of developing the missing or inadequate design files, including the DMRs and DHRs, that meet FDA requirements.

f. In addition to the lack of DHRs for existing products, ADI lacked sufficient DHRs for devices used in the FEMTELLE clinical studies that were submitted in support of the FEMTELLE 510(k) premarket notification. These records cannot be re-created, and thus SAC will have to conduct its own comparative study in order to get this product to market in the United States.

g. ADI had no documented stability program at the time of SAC's acquisition. In other words, ADI did not have real-time stability testing to support the expiration dates provided for the majority of its marketed products. SAC has had to expend time and resources to develop such a stability program and conduct stability testing to support expiration dates for approximately 150 products. In addition, through this testing, SAC determined that certain products did not meet the labeled shelf life, and as a result had to re-label the products and notify customers.

h. ADI had failed to file a 510(k) premarket notification for certain modifications of its products. Specifically, there was no 510(k) submission for Product 826, which combines reagents and test procedures from two other products (Products 810 and 824). Due to the risk of noncompliance with FDA requirements, ADI ceased marketing this product as an IVD device in 2010 and SAC lost sales as a result. ADI may now have to file the 510(k), including

conducting clinical trials, in order to resume marketing Product 826 as an IVD device.

i. ADI's facility did not meet GMP regulations, which SAC is in the process of remedying. For example, the storage areas were insufficient and open to manufacturing activities, there was inadequate space in the shipping and handling area, there was direct exposure of manufacturing areas to air-conditioning ducts, the walk-in coolers were overcrowded, the lyophilizers were not located in appropriate areas, and there was insufficient air supply to the Clean Room as well as no gowning area to the Clean Room from the lyophilization room, among other deficiencies.

j. Certain claims on ADI's product labels were inaccurate or unsubstantiated, requiring correction to bring the labeling process into compliance with FDA requirements, including establishing secure label storage, a label printing control software and assessment system, and update of all labels.

k. ADI's corrective and preventive actions (CAPA) procedure, which involves complaint handling and medical device reporting, was inadequate and not FDA compliant. As a result, SAC was required to modify ADI's CAPA process and hire new personnel.

l. Product 822, known commercially as IMUBIND plasma PAI-1 ELISA, had been manufactured using expired raw materials.

m. In addition to using expired raw materials, Product 822 had to be recalled because it provided a false reading, which could lead to misdiagnosis and the wrong medical treatment.

n. ADI also had several preexisting, undisclosed problems with key customers that ultimately resulted in a decline in business with some of those customers, and a total loss of business with others.

77. As a direct and foreseeable consequence of the numerous breaches identified above, in addition to the damages sustained in remedying those breaches, ADI experienced significant delays in filling its orders, and lost a substantial amount of existing business, including a major customer.

78. Additionally, ADI lost sales of Product 826 when it was pulled from market due to ADI's failure to file a 510(k) when it was owned by Plaintiffs-Counterclaim Defendants, and lost sales of Product 822 due to the required recall as a result of its operational defects.

79. Perhaps most significantly, due to Plaintiffs-Counterclaim Defendants' breaches with respect to the lack of DHRs related to the FEMTELLE 510(k) submission, ADI has been unable to get FEMTELLE to market in the U.S.—which was the primary reason for SAC's purchase of ADI in the first place.

80. On or about October 14, 2010, SAC officially terminated Hart's employment with ADI, and notified Plaintiffs-Counterclaim Defendants of their contractual breaches as provided under the Stock Purchase Agreement.

FIRST COUNTERCLAIM

(Breach of Contract)

81. SAC hereby realleges and incorporates by reference as though fully set forth herein each and every allegation set forth above.

82. SAC and Plaintiffs-Counterclaim Defendants entered into a written contract referred to as the Stock Purchase Agreement, dated March 5, 2009, attached to the Complaint as Exhibit B.

83. The Stock Purchase Agreement is a binding, valid and enforceable contract among SAC, Plaintiffs-Counterclaim Defendants, ADI and other minority shareholders named in the agreement, and is supported by proper consideration.

84. SAC has performed its obligations under the Stock Purchase Agreement.

85. As set forth above, Plaintiffs-Counterclaim Defendants have breached at least paragraphs 4.11, 4.12, 4.14(a), 4.14(c), 4.14(d), 4.14(f) and 4.26 of the Stock Purchase Agreement through their violations of the representations and warranties in those provisions.

86. As a direct result of Plaintiffs-Counterclaim Defendants' breaches of the Stock Purchase Agreement, SAC has suffered actual damages, lost profits and other harm, in an amount to be determined.

87. SAC is also entitled to recover its attorneys' fees and costs pursuant to the terms of the Stock Purchase Agreement.

SECOND COUNTERCLAIM

(Fraud)

88. SAC hereby realleges and incorporates by reference as though fully set forth herein each and every allegation set forth above.

89. Separate and apart from Plaintiffs-Counterclaim Defendants' contractual breaches, Plaintiffs-Counterclaim Defendants made several material representations and omissions regarding the FEMTELLE 510(k) submission, the financial projections for

FEMTELLE, the departure of key employees, and the unavailability of key employees during the due diligence process.

a. Plaintiffs-Counterclaim Defendants falsely represented that FEMTELLE 510(k) clearance was expected by the fourth quarter of 2009 when in fact there was no reasonable expectation that FEMTELLE would ever receive 510(k) clearance based on the 2009 510(k) submission.

b. Plaintiffs-Counterclaim Defendants falsely represented that FEMTELLE's average U.S. sales price would be \$600, with gross margins at 85% and, by 2013, would account for over 80% of ADI's EBITDA.

c. Plaintiffs-Counterclaim Defendants failed to disclose financial information and otherwise hindered SAC's investigation into ADI's operations by firing ADI's long-standing CFO and other members of the accounting staff just before engaging in negotiations with SAC.

d. Plaintiffs-Counterclaim Defendants omitted material information about ADI's compliance issues by making key employees unavailable to SAC during its due diligence.

90. Plaintiffs-Counterclaim Defendants knew their representations and omissions were false and/or misleading at the time they were made, or made such representations and omissions with reckless disregard as to their truth or falsity.

a. Plaintiffs-Counterclaim Defendants knew that the 2009 FEMTELLE 510(k) submission would fail, because they submitted a nearly identical application to the FDA only two years prior that relied on the same studies and tests, which the FDA did not approve.

b. Plaintiffs-Counterclaim Defendants knew that the FEMTELLE projections were grossly misleading because, in addition to their knowledge that 2009 FEMTELLE 510(k) submission would not be approved, the corresponding sales of FEMTELLE in Europe were nowhere near the levels asserted by Plaintiffs-Counterclaim Defendants.

c. Plaintiffs-Counterclaim Defendants knew that SAC would be unable to investigate the details of ADI's finances by firing the individual with the greatest knowledge of these finances, along with those who worked with him, less than one week prior to providing SAC with information regarding ADI.

d. Plaintiffs-Counterclaim Defendants knew that SAC would be unable to discover information about ADI's compliance issues because they kept key ADI employees with knowledge of these issues away from SAC's consultants during the due diligence process.

e. Further, Plaintiffs-Counterclaim Defendants had reason to know of the inadequate condition of the ADI facility at the time of the sale and the numerous other deficiencies identified above.

91. Plaintiffs-Counterclaim Defendants made the misleading statements and omitted information with the intention of defrauding SAC into overvaluing and overpaying for ADI.

92. SAC reasonably relied on the representations to its detriment. Had SAC known the truth regarding the FEMTELLE 510(k), the financial projections for FEMTELLE and the information possessed by the employees who were unavailable to

SAC, as well as the reasons for their unavailability, SAC would not have purchased ADI for \$25.5 million.

93. As a result of the foregoing, SAC has suffered damages in an amount to be determined, or, in the alternative, SAC has the right to rescind the Stock Purchase Agreement into which it was fraudulently induced to enter and to require Plaintiffs-Counterclaim Defendants to repay the purchase price, plus interest.

PRAYER FOR RELIEF

WHEREFORE, SAC respectfully requests judgment as follows:

- A. Dismissing the Complaint with prejudice;
- B. Granting SAC's first counterclaim holding Plaintiffs-Counterclaim Defendants liable for breach of the Stock Purchase Agreement;
- C. Granting SAC's second counterclaim holding Plaintiffs-Counterclaim Defendants liable for fraud;
- D. Awarding damages to SAC according to proof, including, but not limited to, punitive damages, compensatory damages, and consequential damages, including prejudgment and post-judgment interest;
- E. In the alternative, ordering rescission of the Stock Purchase Agreement, including recovery of all consideration paid by SAC plus interest, including prejudgment and post-judgment interest;

- F. Awarding attorneys' fees and costs to SAC; and
- G. Granting SAC such other legal and equitable relief as may be available and as the Court deems just and proper.

Dated: July 9, 2012

MORRISON & FOERSTER LLP

By: /s/ Karen L. Hagberg

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